

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: August 28, 2012  
FINDINGS DATE: September 5, 2012

PROJECT ANALYST: Tanya S. Rupp  
CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: K-8798-12 / Bio-Medical Applications of North Carolina d/b/a FMC Franklin County / Develop a new 10-station dialysis facility in Louisburg by relocating four existing dialysis stations from FMC Warren Hills (Warren County), three existing dialysis stations from BMA Zebulon (Wake County), and three existing dialysis stations from FMC Eastern Wake (Wake County) / Franklin County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications of North Carolina, Inc. (“**BMA**”) d/b/a FMC Franklin County, proposes to establish a new 10-station dialysis facility to provide in-center dialysis and home training for peritoneal dialysis, to be located at the intersection of North Main Street and Smoketree Way in Louisburg, Franklin County. The applicant proposes to relocate the following existing dialysis stations from existing dialysis facilities:

- ◆ Four dialysis stations from the FMC Warren Hills facility in Warren County;
- ◆ Three stations from the BMA Zebulon facility in Wake County, and
- ◆ Three dialysis stations from the FMC Eastern Wake Dialysis Center in Wake County.

Bio-Medical Applications of North Carolina, Inc. is a subsidiary of Fresenius Medical Care Holdings, Inc. BMA will own the dialysis stations proposed in this application, and an

unaffiliated property developer will purchase the land and develop the building. BMA will lease the building from the developer. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. It should be noted that *Table B: ESRD Dialysis Station Need Determination by Planning Area* in the July, 2012 SDR projects a 10 station deficit in Franklin County. However, a footnote to the table clarifies that, since the utilization of existing dialysis stations in a facility in Franklin County is less than 80%, then the need determination is zero. Therefore, neither of the two need methodologies in the *2012 State Medical Facilities Plan (SMFP)* is applicable to the review.

However, SMFP Policy ESRD-2 is applicable to this review. Policy ESRD-2, found on page 33 states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations shall:*

- (A) demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent Dialysis Report, and*
- (B) demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report.”*

The applicant proposes to relocate 10 existing, certified dialysis stations as follows: Four dialysis stations from the FMC Warren Hills facility in Warren County; three stations from the BMA Zebulon facility in Wake County, and three dialysis stations from the FMC Eastern Wake Dialysis Center in Wake County. Thus, the project proposes to increase Franklin County’s inventory by ten dialysis stations, decrease Warren County’s inventory by four, and decrease Wake County’s inventory by eight stations. In addition, Wake and Franklin Counties are contiguous to each other, and Warren County is contiguous to Franklin County. Therefore, three contiguous counties will be affected by this proposal.

The project analyst reviewed the January 2012 Semi-Annual Dialysis Report (SDR), a utilization and projected need report published by the North Carolina State Health Coordinating Council and the Medical Facilities Planning Section. Table B in that report shows a seven station surplus in both Wake and Warren Counties. In addition, the January 2012 SDR, Table B shows a ten-station deficit in Franklin County, the county into which the applicant projects to transfer the stations. The applicant adequately demonstrates that the proposal will not result in a deficit in the number of dialysis stations in either Warren or Wake Counties, the counties that would be losing stations as a result of the proposed project. Furthermore, the applicant adequately demonstrates that the proposal will not result in a surplus of dialysis stations in Franklin County, the county that would gain stations as a result of the proposed project; because the applicant proposes to relocate ten dialysis stations into a

county which the January 2012 SDR has identified as having a deficit of ten dialysis stations. Therefore, the application is conforming to Policy ESRD-2, and is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

NC

Currently, there is one dialysis facility in Franklin County, located in Louisburg. Dialysis Care of Franklin County, operated by DaVita, Inc. is a 23-station dialysis facility located in Louisburg. The January, 2012 SDR shows that Dialysis Care of Franklin County was operating at 79% utilization, with 73 in-center patients dialyzing on 23 stations [73 / 23 = 3.17; 3.17 / 4 = 79.3].

In this application, BMA proposes to establish a new 10-station dialysis facility in Louisburg, Franklin County, by relocating four existing dialysis stations from the FMC Warren Hills facility in Warren County; three existing dialysis stations from the BMA Zebulon facility in Wake County, and three existing dialysis stations from the FMC Eastern Wake facility. In Section III.3(b), page 41, the applicant projects that 30 existing dialysis patients will initially transfer to the new facility in Louisburg. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

Population to be Served

In Section III.7, page 49, the applicant projects that 100% of the patients to be served at the proposed facility will be residents of Franklin County, as shown in the table below:

FMC FRANKLIN COUNTY	12/31/2013		OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Franklin	29.9	2.3	32.1	3.5	34.5	5.7	100%	100%
Total	29.9	2.3	32.1	3.5	34.5	5.7	100%	100%

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to relocate ten existing, certified dialysis stations from existing facilities in Wake and Warren Counties to develop a new facility in Franklin County, in

which the applicant projects the stations will be utilized at 80% by the end of the first year of operation, with 32 patients dialyzing on 10 in-center dialysis stations.

In Section III.3, pages 40 - 41, the applicant states,

*“BMA proposes to relocate 10 dialysis stations to develop the FMC Franklin County facility. Within this application, BMA has projected to be serving 32 patients at the end of the first year of operations for this facility; this equates to an 80% utilization rate or 3.2 patients per station. ... This is an application to transfer a total of 10 dialysis stations from three BMA facilities; the facility is projected to be serving 3.2 patients per station at the end of the first operating year. BMA has included letters of support from in-center dialysis patients, each indicating that they live closer to Louisburg and that the proposed FMC Franklin County facility would be a more convenient setting for their dialysis treatment. BMA has projected that 30 dialysis patients would transfer to this facility and that the facility census of Franklin County patients would increase at an average annual rate of 7.3% as discussed within this application.”*

In Section III.7, pages 50 - 51, the applicant presents a more detailed methodology along with its assumptions for projecting to serve 34 in-center patients by the end of the second year of operation. The applicant states:

- 1. “BMA assumes that the patient population of FMC Franklin County will be comprised of patients from Franklin County. BMA is serving a significant number of Franklin County dialysis patients at its facilities in Warren and Wake Counties.*
- 2. BMA assumes that the patient population of Franklin County will grow at a rate commensurate with the Franklin County Five Year Average Annual Change Rate as published in the January 2012 SDR. That rate is 7.3%.*
- 3. BMA also assumes after the facility is certified, that the home peritoneal dialysis patient population residing in Franklin County and currently served by BMA will transfer their care to FMC Franklin County. Further, as the ESRD home patient population increases, some home PD patients will begin their care with the new BMA facility.*

*The January 2012 SDR reports that there were 18 home patients residing within Franklin County. This represented 15.7% of the total County ESRD) population. BMA is **NOT** projecting that patients currently served by the DaVita dialysis facility in Louisburg will transfer their care. Rather, BMA is suggesting that the PD patients currently served by BMA and residing in Franklin County will transfer their care to the facility. In addition, BMA projects that some of the future home patients from Franklin County will choose FMC Franklin County as their dialysis provider. (BMA will not prohibit any patient from changing providers; the*

*only requirement is proper referral from a physician with admitting privileges at the facility).* [emphasis in original]

*BMA does not assume that all of the new home patients of Franklin County will transfer their care to the new FMC Franklin County. Rather, BMA assumes that only one new home PD patient will utilize FMC Franklin County in the first year of operations, and that two new PD patients will utilize the facility in the second year of operations. This is not to say that BMA will restrict patient admissions to the home PD program, but rather that BMA will utilize extremely conservative projections for the purposes of this application. See the methodology discussion for further explanation.*

4. *BMA is providing treatment for 30 in-center dialysis patients at its dialysis facilities in Wake and Warren Counties.*
5. *The January 2012 SDR reports that the DaVita facility in Louisburg was underutilized on June 30, 2011 with a reported 79.35% utilization rate.*
6. *In his letter of support, Dr. Koenig, Medical Director for the proposed FMC Franklin County facility, and a physician member of the Capital Nephrology Associates, has indicated that he and his associates would extend their practice footprint into Franklin County by seeking admitting privileges at the Franklin Regional Medical Center in Louisburg. The significance of this is that Dr. Koenig and his associates are already serving a significant portion of the Franklin County ESRD patient population.*
7. *BMA assumes that this proposal is consistent with Policy ESRD 2. ESRD 2 says in part, “Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility “. [Emphasis added] Each of the facilities contributing dialysis stations to this proposal is currently serving at least one patient from Franklin County.*
8. *Further, the relocation of these stations will not create a surplus of stations in Franklin County, nor will the relocations create a deficit in the counties losing stations. See discussion specific to Policy ESRD 2.*
9. *This project is scheduled for completion and certification of stations at December 31, 2013. Thus, Operating Year 1 is the period from January 1, 2014 through December 31, 2014. Operating Year 2 is the period from January 1, 2015 through December 31, 2015.”*

Therefore, based on the information in Sections III.3 and III.7, the applicant states that 30 patients will initially transfer their treatment to the proposed Franklin County facility when it

is operational. In Section III.3, page 41, the applicant further states “*as an alternative, BMA has demonstrated that the 25 patients who have signed letters of support for this project will increase to 30 patient [sic] at the time this project is scheduled for completion.*”

In Exhibit 22, the applicant provides 25 letters signed by current BMA patients as evidence of those patients’ willingness to transfer their care to FMC Franklin when the facility is certified. Each letter includes the patient name, the name of the dialysis facility in which the patient currently receives treatment, and the county and ZIP code of the patient residence. The project analyst prepared the following table to illustrate the information contained in the patient letters:

<b>RESIDENCE ZIP CODE</b>	<b>CITY</b>	<b>CURRENT DIALYSIS FACILITY/COUNTY</b>	<b># LETTERS SIGNED</b>
27597	Zebulon	BMA Zebulon / Wake	2
27596	Youngsville	FMC Eastern Wake / Wake	4
27882	Spring Hope	BMA Zebulon / Wake	1
27587	Wake Forest	BMA Zebulon / Wake	1
27549	Louisburg	BMA Zebulon / Wake	4
		FMC Eastern Wake / Wake	3
		FMC Warren Hills / Warren	1
		Wake Dialysis / Wake	1
27525	Franklinton	FMC Eastern Wake / Wake	3
		Wake Dialysis / Wake	1
27508	Bunn	BMA Zebulon / Wake	3
		FMC Eastern Wake / Wake	1
<b>Total Letters</b>			<b>25</b>
<b>Total Letters from Out of County Residents</b>			<b>3</b>

Two of the letters are signed by patients who state they are residents of Wake County, and one letter is signed by a patient who states he is resident of Nash County. In Section III.7, page 49, the applicant projects that 100% of the patients to be served will be residents of Franklin County. Therefore, the letters signed by patients who reside in Wake and Nash Counties cannot be counted as patients who are residents of Franklin County who wish to transfer their dialysis treatments to a Franklin County facility. Thus, the applicant provides evidence that supports 22 existing in-center dialysis patients who are residents of Franklin County will consider transferring to the Franklin County facility when it becomes operational. Below is a table which illustrates the project analyst’s growth calculations of a beginning census of 22 in-center patients in Franklin County, using the Five Year Average Annual Growth Rate (AACR) of 7.3 from the January 2012 SDR:

Begin with 22 in-center patients who signed letters, as of December 31, 2011	22
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Project this population forward one year to December 31, 2012 using the Franklin County AACR of 7.3%.	$(22 \times 0.073) + 22 = 23.6$
Project this population forward one year to December 31, 2013 using the Franklin County AACR of 7.3%	$(23.6 \times 0.073) + 23.6 = 25.3$
Project this population forward one year to December 31, 2014 using the Franklin County AACR of 7.3%. This is the end of OY 1	$(25.32 \times 0.073) + 25.32 = 27.2$
Project this population forward one year to December 31, 2015 using the Franklin County AACR of 7.3%. This is the end of OY 2.	$(27.2 \times 0.073) + 27.2 = 29.2$

Performance Standards for dialysis facilities as codified in 10A NCAC 14C .2203(a) requires an applicant to “document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility....” In this application, the applicant demonstrates that it will serve a total of 27 in-center patients on 10 stations at the end of the first operating year, which is 2.7 patients per station per week, or a utilization rate of 67.5%. Therefore, the applicant has not demonstrated that the proposed BMA Franklin facility would meet the minimum performance standard requirements outlined in the statute. Even if the project analyst were to assume that all of the letters signed by patients can be counted as patients who will transfer their care to FMC Franklin County, 25 in-center patients will not grow to 30 by the projected completion date of December 31, 2013, as stated by the applicant on page 41 [ $25 \times 1.073 = 26.85$  as of 12/31/12;  $26.85 \times 1.073 = 28.78$  as of 12/31/13]. Furthermore, a beginning census of 25 in-center patients will not grow to 32 patients at the end of the first year of operation, as required by the statute. See the following calculations:

- Begin with 25 patients as of December 31, 2011
- $25 \times 1.073 = 26.8$  patients as of December 31, 2012
- $26.8 \times 1.073 = 28.8$  patients as of December 31, 2013 (facility certification)
- $28.8 \times 1.073 = 30.8$  patients as of December 31, 2014 (PY 1)

Thus, the applicant erroneously projects that 30 patients will initially transfer to the facility upon project completion or, in the alternative, 25 patients pursuant to the patient letters in Exhibit 22.

In addition, in Section III.8, page 51, the applicant provides a chart which projects growth of 26 in-center dialysis patients, using the Franklin County 7.3% Five Year Average Annual Change Rate (AACR) published in the January 2012 SDR. See the following table, from page 51:

BMA begins with the 26 in-center patients currently served as of December 31, 2011.*	26 in-center patients
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BMA projects this patient population forward for 12 months to December 31, 2012 using a growth rate of 7.3% as discussed.	$(26 \times .073) + 26 = 27.9$
BMA projects this patient population forward for 12 months to December 31, 2013 using the growth rate of 7.3%. This is the projected beginning census for the new facility.	$(27.9 \times 0.73) + 27.9 = 29.9$
BMA projects this patient population forward for 12 months to December 31, 2014. This is the end of Operating Year 1.	$(29.9 \times .073) + 29.9 = 32.1$
BMA projects this patient population forward for 12 months to December 31, 2015. This is the end of Operating Year 2.	$(32.1 \times .073) + 32.1 = 34.5$

\*The applicant includes the home patients served and adds them to the total after calculating growth. The project analyst chose to omit the addition of the home patients since the utilization is calculated based on in-center patients.

However, the applicant does not provide any information to explain how it arrived at a beginning census of 26 in-center patients, as shown on page 51; particularly when considered with the applicant’s projections of serving 30 patients initially and “*as an alternative,*” 25 patients. Thus, the information provided by the applicant is inconsistent and thus unreliable with regard to how many patients it projects to serve at the proposed facility.

If the project analyst were to accept all 25 patient letters as evidence of patients who will transfer their care to the proposed FMC Franklin facility, and if the analyst were to assume that the patient population would grow to a census sufficient to allow the facility to meet the minimum utilization requirement, the applicant still has not demonstrated the need for a facility in the proposed location in Louisburg. See the following table, prepared by the project analyst:

**Distance from BMA Patient Residence ZIP Code to Current BMA Facility\***

RESIDENCE ZIP	BMA ZEBULON (27597)		FMC EASTERN WAKE (27571)		FMC WARREN HILLS (27589)		FMC WAKE DIALYSIS (27609)	
	# PTS.	MILES TO FACILITY	# PTS.	MILES TO FACILITY	# PTS.	MILES TO FACILITY	# PTS.	MILES TO FACILITY
27597	2	--	--	--	--	--	--	--
27596	0	--	4	11.08	--	--	--	--
27882	1	14.35	--	--	--	--	--	--
27587	1	18.75	--	--	--	--	--	--
27549	4	26.95	3	19.28	1	26.34	1	34.45
27525			3	16.11	--	--	1	23.26
27508	3	10.68	1	14.18	--	--	--	--
Total	11		11		1		2	

\*Mileage distances are from Mapquest, and are rounded by the project analyst.  
 Table prepared by project analyst

The table above shows that 9 patients, or 36% of the total who signed letters, currently travel 15 miles or less to their current BMA dialysis facility for treatment; 7 patients, or 28%, currently travel 15 - 20 miles for their treatment; and 7 patients, or 28%, currently travel over 20 miles for

their dialysis treatments [2 are residents of ZIP code 27597, the same ZIP code in which their dialysis facility is located].

By contrast, see the following table prepared by the project analyst to show distance from the reported patient residence ZIP codes to the proposed FMC Franklin County facility ZIP code:

**Distance from Patient Residence ZIP to Proposed FMC Franklin**

<b>PT. RESIDENCE TOWN</b>	<b>PT. RESIDENCE ZIP</b>	<b>NUMBER OF PTS.</b>	<b>DISTANCE TO 27549</b>
Zebulon	27597	2	26.94 Miles
Wake Forest	27587	1	22.88 Miles
Youngsville	27596	4	22.86 Miles
Rolesville	27882	1	16.48 Miles
Franklinton	27525	4	14.36 Miles
Bunn	27508	4	14.20 Miles
Louisburg	27549	9	--

\*Source: Mapquest search, zip codes from application

Based on the information in the above table, 17 patients, or 68% will travel less than 15 miles for dialysis treatment [9 patients are residents of 27549, the same ZIP code as the proposed facility]; 1 patient, or 4% will travel from 15 to 20 miles for dialysis treatment; and 7 patients, or 28% will travel more than 20 miles for dialysis treatment. Therefore, while the percentage of patients who will travel less than 20 miles increases, the percentage of patients who will travel over 20 miles remains the same. It is therefore not clear from the information presented by the applicant how it anticipates that 30 of its current patients will travel from existing BMA facilities to the proposed Louisburg location, when only 18 patients will actually see a reduction in travel. If the Agency were to assume that only these 18 patients who will actually reduce their travel time will transfer to the proposed facility, the utilization is insufficient to support a ten-station dialysis facility [18 patients / 10 stations = 1.8 patients per station]. Moreover, if we allow for growth based on the January 2012 Semi-Annual Dialysis Report based on a 7.3% Five Year AACR for Franklin County, then a beginning census of 18 patients grows to only 20.7 in-center patients by project year two [18 x 1.073 = 19.3 at PY 1; 19.3 x 1.073 = 20.7 at PY 2]. Therefore, the applicant has not provided sufficient information to adequately demonstrate the facility will meet the required performance standards pursuant to 10A NCAC 14C .2303, which requires utilization of 3.2 patients per station per week at the end of the first operating year.

The applicant also provides a map in Section III and in Exhibit 27 with which it illustrates the proximity of existing BMA patients to the proposed FMC Franklin facility location in Louisburg. In Section III.3, page 46, the applicant states:

*“In selecting a locale for development of this project, BMA considered the residence location of the current patient population served by BMA and the future patient population of the facility .... BMA has worked closely with Capital Nephrology for many years. Collaboration with Capital Nephrology indicates that they are serving a large number of Stage 3, 4, and 5 Chronic Kidney Disease patients who reside in Franklin County. Working together, we have determined*

*that the overwhelming majority of these future dialysis patients reside within the center of Franklin County. Thus, BMA considered developing the facility in Louisburg which is essentially the center of the county. Further consideration was given to the location of the hospital. After careful consideration of the current patient population, the probable future patient population of the County and the location of the hospital, BMA has elected to develop the facility in Louisburg as opposed to another area of the County.”*

The applicant provides a Franklin County map on page 46 with blue dots in it, which the applicant reports represent the residence location of existing BMA patients who would benefit from a facility in Louisburg. A larger map is provided in Exhibit 27, Map 1. However, analysis of these maps contradicts the applicant’s statements. There are a total of 25 blue dots within the Franklin County border, and two blue dots which are located on the borders (one on the border of Franklin and Nash County, and one on the border of Franklin and Wake County). Two of the dots are in the center of the county, and two are very nearly in the center, to the north and the northeast. Five of the blue dots are slightly to the south and southwest. Five dots are nearly on the western border of the county, five dots are nearly on the southern border with Wake County, and five dots are to the east near Nash County. Thus, 15 blue dots, representing 15 patient residence locations, are closer to the southern, eastern, and western borders of Franklin County. BMA has three facilities in Northern Wake County, and one facility in Eastern Nash County, which would be closer to the dots represented on the map supplied by the applicant. Thus, the majority of patients represented by blue dots actually live to the south, southeast, and southwest of the center of Franklin County, according to the map supplied by the applicant.

In this application, the applicant proposes to develop a 10-station dialysis facility by relocating existing stations and transferring existing patients. However, the applicant failed to reasonably demonstrate that a sufficient number of patients will transfer to the facility, since the numbers of patients the applicant states will transfer is inconsistent. Furthermore, the number of patients for which there is evidence of possible transfer is insufficient to satisfy the requirements of 10A NCAC 14C .2203(a). In addition, the applicant failed to substantiate the need for an additional dialysis station in Franklin County, since the existing dialysis facility has been consistently underutilized for the past three years. In summary, the applicant failed to adequately demonstrate the need to establish a 10-station dialysis facility in Louisburg. Consequently, the application is not conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

The applicant proposes to establish a new dialysis facility in Louisburg by transferring existing dialysis stations from existing facilities in two contiguous counties. In Section III.3, page 29, the applicant states:

*“This proposal is designed to make more effective use of existing certified dialysis stations. As noted in ... Section II of this application..., there is currently a surplus of dialysis stations in Wake and Warren Counties and a deficit of stations in Franklin County. BMA proposes to mitigate the Franklin County deficit by transferring surplus stations to Franklin County. This action will not create a station deficit within Wake or Warren Counties, nor will it create a station surplus in Franklin County. The transferring facilities, FMC Warren Hills, BMA Zebulon, and FMC Eastern Wake are **currently serving** patients from Franklin County.” [emphasis in original].*

In Section III.3(c), pages 41 – 45, the applicant describes the impact of the proposed transfer of stations from each facility that will donate stations to the proposed FMC Franklin facility. On pages 41 – 42, with regard to the FMC Warren Hills facility, the applicant states:

*“FMC Warren Hills*

*FMC Warren Hills is currently certified for 25 dialysis stations. According to the January 2012 SDR, the facility was operating at 77.78% utilization with 56 patients dialyzing on 18 stations as of June 30, 2011. As December 31, 2011 the facility had 62 patients dialyzing on 25 stations for a utilization rate of 62%% [sic].*

*Transferring four stations from FMC Warren Hills to FMC Franklin County will result in the facility having 21 stations. In this application, BMA projects that one Franklin County patient will transfer from FMC Warren Hills to the FMC Franklin County facility upon completion of the project and certification of the stations at FMC Franklin County. The following table identifies the county of residence for the patients at FMC Warren Hills as of June 30, 2010:”*

<b>FMC WARREN HILLS CENSUS: DECEMBER 31, 2011</b>	<b># PTS. DIALYZING IN-CENTER</b>
Warren	52
Vance	1
Franklin	1
Halifax	7
Brunswick, VA	1
<b>Total</b>	<b>62.0</b>

On pages 41 – 42, the applicant states:

*“In addressing the needs of patients continuing to dialyze at FMC Warren Hills subsequent to the transfer of four stations to FMC Franklin County, BMA will project growth of the FMC Warren Hills patient population to the projected date of project completion and certification of the new FMC Franklin County facility: December 31, 2013. However, BMA will only project a change in the Warren County ESRD patient population of FMC Warren Hills. The patients from Vance, Franklin, Halifax and Brunswick (VA) Counties Warren are assumed to be dialyzing at FMC Warren Hills as a function of patient choice. With the exception of the patient from Franklin County, BMA assumes that these patients will continue to dialyze at FMC Warren Hills, but does not project any change to this portion of the FMC Warren Hills patient census; the patients from other counties are added back to the projected number of FMC Warren Hills in-center dialysis patients as of December 31, 2013. BMA does project the patient from Franklin County will transfer at the time this project is completed.”*

In projecting utilization of the Warren Hills facility following the station relocation and patient transfer, the applicant states it will only project growth of the Warren County patients. See the following table, from page 42 of the application:

In-center patient population who are residents of Warren County as of December 31, 2011	52
Using Five Year AACR from January 2012 SDR, project growth to December 31, 2012	$(52 \times 0.061) + 52 = 55.2$
Project growth to December 31, 2013 (Projected certification date of FMC Franklin County)	$(55.2 \times 0.061) + 55.2 = 58.6$
Project utilization, adding back the 10 patients from other counties as identified in table above, minus one patient projected to transfer with the stations to FMC Franklin County	$58.6 + 10 = 68.6$ $68.6 - 1 = 67.6$ $67.6 / 21 = 3.2$ $3.2 / 4 = 0.80$

The applicant demonstrates that the remaining dialysis stations at the FMC Warren Hills facility will continue to be adequately utilized following the proposed relocation.

In Section III.3(c), pages 42 – 43, the applicant describes the impact of the proposed transfer of stations from the BMA Zebulon facility:

*“BMA Zebulon*

*BMA Zebulon is currently certified for 30 dialysis stations. According to the January 2012 SDR, the facility was operating at 70.83% utilization with 85 patients as of June 30, 2011. As of December 31, 2011 the facility had 89 patients.*

*Transferring three stations from BMA Zebulon to FMC Franklin County will result in the facility having 27 stations. In this application, BMA projects that six Franklin County patients will transfer from BMA Zebulon to the FMC Franklin County facility upon completion of the project and certification of the stations at*

*FMC Franklin County. The following table identifies the county of residence for the patients at FMC Warren Hills as of December 32, 2011:*

<b>BMA ZEBULON CENSUS: DECEMBER 31, 2011</b>	<b># PATIENTS DIALYZING IN- CENTER</b>
<i>Wake</i>	63
<i>Franklin</i>	6
<i>Johnston</i>	4
<i>Wilson</i>	2
<i>Nash</i>	13
<i>Vance</i>	1
<b>Total</b>	<b>89</b>

In projecting utilization of the BMA Zebulon facility following the station relocation and patient transfer, the applicant states it will only project growth of the Wake County patients. See the following table, from page 43 of the application:

In-center patient population who are residents of Wake County as of December 31, 2011	63
Using Five Year AACR from January 2012 SDR, project growth to December 31, 2012	$(63 \times 0.059) + 63 = 66.7$
Project growth to December 31, 2013 (Projected certification date of FMC Franklin County)	$(66.7 \times 0.059) + 66.7 = 70.7$
Project utilization, adding back the 26 patients from other counties as identified in table above, minus six patients projected to transfer with the stations to FMC Franklin County	$70.7 + 26 = 96.7$ $96.7 - 6 = 90.7$ $90 / 27 = 3.3$ $3.3 / 4 = 0.825$

Thus, the applicant projects the BMA Zebulon facility will operate at an 82.5% utilization rate, with 90 in-center patients dialyzing on 27 stations as of December 31, 2013, the projected certification date of the proposed FMC Franklin facility. The stations remaining at BMA Zebulon in Wake County following that station relocation would continue to adequately serve those dialysis patients who are residents of Wake County. Similarly, the relocation of dialysis stations and transfer of dialysis patients to Franklin County would reasonably serve those Franklin County residents who prefer to dialyze in a facility in Franklin County.

The applicant adequately demonstrates that the FMC Zebulon facility will not be underutilized or overcrowded following the transfer of stations to FMC Franklin.

In Section III.3(c), pages 44 – 45, the applicant describes the impact of the proposed transfer of stations from the FMC Eastern Wake facility:

*“FMC Eastern Wake*

*FMC Eastern Wake is currently certified for 14 dialysis stations. According to the January 2012 SDR, the facility was operating at 80.36% utilization with 45 patients as of June 30, 2011. As December 31, 2011 the facility had 40 patients dialyzing on 14 stations.*

*Transferring three stations from FMC Eastern Wake to FMC Franklin County will result in the facility having 13 stations. Assuming the present census the resultant utilization would be 3.15 patients per station.*

*In this application, BMA projects that 12 Franklin County patient [sic] will transfer from FMC Eastern Wake to the FMC Franklin County facility upon completion of the project and certification of the stations at FMC Franklin County.”*

The project analyst concludes that the reference to the FMC Eastern Wake facility being certified for 13 dialysis stations after the transfer of three stations proposed in this application, is a typographical error. Transferring three stations, as proposed in this application, will result in a facility total of 11 certified dialysis stations following completion of this project. The applicant’s utilization calculations, the analysis of which follows, are based on a future station complement of 11, consistent with the information in the July SDR.

In projecting utilization of the FMC Eastern Wake facility following the station relocation and patient transfer, the applicant states it will only project growth of the Wake County patients, because it projects that all 12 Franklin County patients who currently dialyze at FMC Eastern Wake will transfer their care to FMC Franklin County when the project is certified. See the following table, from page 44 of the application:

In-center patient population who are residents of Wake County as of December 31, 2011	28
Using Five Year AACR from January 2012 SDR, project growth to December 31, 2012	$(28 \times 0.059) + 28 = 29.7$
Project growth to December 31, 2013 (Projected certification date of FMC Franklin County)	$(29.7 \times 0.059) + 29.7 = 31.4$
Project utilization of 31 patients on 11 in-center stations	$31 / 11 = 2.8$ $2.8 / 4 = 0.705$

In this instance, the applicant proposes to relocate three existing dialysis stations from FMC Eastern Wake in Wake County, and transfer 12 Franklin County patients. The applicant proposes to relocate three existing dialysis stations from a Wake County dialysis facility, along with 12 existing patients who are residents of Franklin County, to a dialysis facility in Franklin County. The stations remaining at the Wake County dialysis facility would continue to adequately serve those dialysis patients who are residents of Wake County. Similarly, the relocation of dialysis stations and transfer of dialysis patients to Franklin County would reasonably serve those Franklin County residents who prefer to dialyze in a facility in Franklin County.

Thus, the applicant projects the FMC Eastern Wake facility will operate at a 70.5% utilization rate, with 31 in-center patients dialyzing on 11 stations as of December 31, 2013, the projected certification date of the proposed FMC Franklin facility. Although the FMC Eastern Wake facility will be underutilized following the relocation of stations to the FMC Franklin facility, the applicant demonstrates that the needs of the population presently served at the FMC Eastern Wake facility will continue to be adequately served, since the facility will still not be operating at full capacity.

The applicant proposes to develop a new 10-station dialysis facility in Louisburg in Franklin County, by relocating existing stations from Wake and Warren Counties. The applicant adequately demonstrates that the three facilities from which dialysis stations would be transferred would be adequately utilized following the station relocation. Thus, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed dialysis station relocation. See Criterion (3) for additional discussion regarding the proposed transfer of stations. Therefore, the application is conforming to this criterion.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC

In Section III.9, page 52, the applicant discusses the alternatives it considered prior to submitting this application, which include

- a) not developing the proposed facility at all, which was rejected because the applicant states it currently serves Franklin County residents and projects the population to increase.
- b) selecting a different location within Franklin County to develop the facility. This proposal was rejected because the applicant states Louisburg is the most “logical” choice, given the current residence of existing patients.

After considering those alternatives, the applicant states the alternative represented in the application is the best alternative.

However, the applicant’s proposal to relocate only one patient and four dialysis stations from FMC Warren Hills is unreasonable and impractical. Relocating four dialysis stations from the FMC Warren Hills facility to serve only one Franklin County patient is not a cost-effective use of health care resources. Four dialysis stations have the capability to serve up to 16 patients at 2 shifts per day, 6 days per week. It is illogical to propose to relocate four stations from Warren County, to serve only one Franklin County resident, in order to establish a new 10-station dialysis facility.

The applicant’s proposal to relocate three existing dialysis stations from BMA Zebulon in Wake County and transfer six Franklin County patients is likewise unreasonable and impractical. One dialysis station has the capability to serve up to four patients. In this

proposal, the applicant proposes to relocate three existing dialysis stations, which have the capability to serve up to 12 patients, from a Wake County dialysis facility, along with the six existing patients who are residents of Franklin County, to a dialysis facility in Franklin County. Six patients could reasonably be served on two dialysis stations.

Moreover, the applicant did not demonstrate that an additional dialysis facility is needed in Franklin County, for the following reasons:

1. The applicant provided inconsistent information regarding the number of patients projected to transfer to the facility; therefore, there is an insufficient number of patients to justify a new 10-station facility, pursuant to 10A NCAC 14C .2303.
2. The applicant failed to demonstrate that a new dialysis facility in Louisburg would in fact be closer to patients' homes, as there are as many patients residing in Southwest Franklin County as there are in Louisburg.
3. The applicant failed to document the need for an additional 10-station dialysis facility in Franklin County.

The application is not conforming to all other applicable statutory and regulatory review criteria. The applicant failed to adequately demonstrate that the proposal is its least costly or most effective alternative. Consequently, the application is not conforming to this criterion.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

#### NC

In Section VIII.1, page 73, the applicant projects that the total capital cost will be \$1,441,884, including \$1,068,607 in construction costs, \$54,050 for water treatment equipment, \$130,454 for additional equipment, and \$188,773 in Architect and Engineering fees and contingencies. In Section VIII.2, page 51, the applicant states Fresenius Medical Care, Inc., parent company of BMA, will finance the project with accumulated reserves. In Section IX.3, page 79, the applicant states there will be \$57,177 in start-up expenses. In Section IX.2, page 78, the applicant states there will be \$981,027 in initial operating expenses, for total working capital requirement of \$1,038,204. In Exhibit 24 the applicant provides a March 15, 2012 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

*"This is to inform you that Fresenius Medical Care Holding, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*

*BMA proposes to develop a new 10 station dialysis facility in Louisburg, Franklin County by transferring 10 existing and certified dialysis stations from contiguous*

counties into Franklin County. The project calls the following capital expenditures on behalf of BMA.

*Capital Expenditure* *\$1,441,884*

*As Vice President, I am authorized and do hereby authorize the development of this 10 station dialysis facility, Fresenius Medical Care of Franklin County, for capital costs of \$1,441,884. Further, I am authorized and do hereby authorize and commit all necessary cash and cash reserves for the start up and working capital which may be needed for this project.”*

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2009 and 2010. As of December 31, 2010, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$163,292,000 with \$12,017,618,000 in total assets and \$6,561,629,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of funds for the capital needs of the project.

The Medicare/Medicaid rates in Section X.1 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application, pages 81 - 84. The applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	<b>PY1</b>	<b>PY 2</b>
Net Revenue	\$1,541,768	\$1,730,420
Operating Expenses	\$1,471,541	\$1,608,563
Profit	\$70,227	\$121,857

The rates in Section X.1, page 80 are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. In the revenue and expense statements in Sections X.2, X.3, and X.4, pages 81 - 84, the applicant projects that revenues will exceed operating costs in each of the first two years of operation. However, the assumptions used by the applicant in preparation of the pro forma financial statements, including the projection of the number of patients served and the treatments to be provided are not reasonable. See Criterion 3 for discussion of the applicant’s assumptions and projections.

In summary, the applicant adequately demonstrated the availability of sufficient funds for the immediate financial feasibility and the capital needs of the proposal, but failed to adequately demonstrate the long term financial feasibility of the project. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

The applicant proposes to develop a new 10-station dialysis facility in Louisburg by transferring existing stations from three BMA facilities in Wake and Warren Counties. The applicant did not demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. There is one dialysis facility currently located in Louisburg, which is less than two miles from the proposed FMC Franklin location, according to Mapquest®. The project analyst reviewed the Semi Annual Dialysis Reports from July 2009 to July 2012, and found the following utilization data:

DATE OF SDR	# PATIENTS	# STATIONS	% UTILIZATION
July 2012	70	23	76%
January 2012	73	23	79%
July 2011	71	23	77%
January 2011	70	23	76%
July 2010	70	23	76%
January 2010	76	23	82%
July 2009	75	23	81%
January 2009	73	23	79%
<b>Average Utilization January 2009 to July 2012</b>			<b>78%</b>

The data shows that the existing facility in Louisburg has consistently operated below 80% utilization for the past three years; and has operated below 80% utilization for six of the last eight SDR reporting periods.

Additionally, the applicant did not demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities for the following reasons:

1. The applicant did not provide sufficient, reasonable, or credible evidence to support the projected number of patients (32) to be served by the end of the first project year would meet the utilization requirements codified in 10A NCAC 14C .2203(a), at 3.2 patients per station per week.
2. The applicant failed to demonstrate the need for its proposed facility in the town of Louisburg; particularly since the existing dialysis facility in Louisburg has been underutilized, and only 9, or approximately one-third, of the current patients it proposes to serve reside in the Louisburg ZIP code. An additional 9 patients reside in Southwest Franklin County, in the general vicinity of Franklinton and Youngsville.
3. The applicant's reliance upon the patient letters included to substantiate projected utilization is not reasonable in this application. Three of the letters are from patients residing in counties other than Franklin, the only county projected by the applicant to be served at the proposed facility.
4. Additionally, the patients in the Bunn area of Southeast Franklin County are as near to the BMA facility in Zebulon and the BMA facility in Spring Hope. Moreover, FMC Spring Hope in Nash County, from which a patient signed a letter supporting this application, was approved in June 2012 to add three dialysis stations (see Project ID Number L-8796-12).

For the reasons listed above, the utilization projections given by the applicant are unsubstantiated and thus unreliable. The applicant has not shown how the facility proposed in this application would benefit existing and future dialysis patients. Therefore, a second provider of dialysis services in the area, as proposed in this application, would result in unnecessary duplication of existing dialysis services in Franklin County.

Thus, the applicant has not demonstrated that this proposal would not result in the unnecessary duplication of existing or approved dialysis services or facilities in Franklin County. Therefore, the application is not conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, page 69, the applicant projects the number of FTE positions following completion of the proposed project, as illustrated in the table below.

POSITION	PROJECTED # OF FTES
RN	1.00
Tech	3.00
Clinical Manager	1.00
Medical Director	Contract Position
Administration	0.15
Dietitian	0.20
Social Worker	0.25
Home Training Nurse	0.67
Chief Tech	0.15
Equipment Tech	0.35
In-Service	0.15
Clerical	0.75
<b>Total</b>	<b>7.67</b>

In Section V.4(c), page 60, the applicant states Dr. Daniel Koenig will be the Medical Director for FMC Franklin. In Exhibit 21, the applicant provides a March 15, 2012 letter signed by Dr. Koenig that confirms his commitment to serve as Medical Director. In Exhibit 23 the applicant provides a copy of Dr. Koenig's curriculum vitae, which confirms he is board-certified in internal medicine. In Section VII.4, page 70, the applicant states it anticipates no difficulty in hiring the necessary staff for the FMC Franklin dialysis facility, and describes the experience it has in recruiting and hiring staff necessary to operate dialysis facilities. The additional information provided in Application Sections V and VII is reasonable and credible and supports a finding of conformity to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and

support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Application Section V.1, page 56, the applicant lists the providers of the necessary ancillary and support services to be provided for the proposed facility. The information regarding coordination of services in Section V.1, page 56, of the application and referenced exhibits is reasonable and credible and supports a finding of conformity with this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section XI.6(g), page 92 of the application, the applicant states it will construct 8,000 square feet of space for the proposed dialysis facility in Louisburg. In Section XI.6(d), pages

90 - 91 of the application, the applicant states that applicable energy saving features and water treatment equipment will be incorporated into the construction plans in the following ways:

- ◆ HVAC system operating efficiency will equal “*industry standards for high seasonal efficiency.*”
- ◆ Facility will use energy efficient exit signs, external insulation wrap for hot water heaters, water flow restrictors at sink faucets, and other methods of energy conservation.
- ◆ Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors, which use less amperage.

The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2009, respectively. The data in the table was obtained on April 4, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	TOTAL # OF MEDICAID ELIGIBLES AS % OF TOTAL POPULATION	TOTAL # OF MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION	% UNINSURED CY 2008 (ESTIMATE BY CECIL G. SHEPS CENTER)
Franklin	18%	7.3%	19.7%
Statewide	17%	2.4%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by FMC Franklin.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

In Section VI.1(a), page 65, the applicant states:

*“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”*

In Section VI.1(b), page 66, the applicant provides a table which illustrates the historical payor mix for the other BMA facilities that are contributing stations to the proposed facility, and thus are in counties that are contiguous to Franklin County. See the following table:

**Historical Payor Source;  
 Other BMA Facilities**

<b>PAYOR SOURCE</b>	<b>IN-CENTER</b>
Commercial Insurance	12.0%
Medicare	79.6%
Medicaid	6.8%
VA	1.4%
Other: Self/Indigent	0.2%
<b>Total</b>	<b>100.0%</b>

The Centers for Medicare & Medicaid Services (CMS) website states:

*“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...*

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population.*

*In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”<sup>1</sup>*

Additionally, the United States Renal Data System, in its *2011 USRDS Annual Data Report* shows the following statistics for FY 2009 in Network 6, which includes North Carolina, South Carolina, and Georgia:

**Percent of Dialysis Patients by Race/  
Ethnicity**

RACIAL GROUP	% OF DIALYSIS POPULATION
White/Caucasian	30.5%
African American	67.2%
Native American	0.6%
Asian	1.1%
Hispanic	2.6%

**Percent of Dialysis Patients by Age**

AGE GROUP	% OF DIALYSIS POPULATION
0 – 19	0.35%
20 – 44	13.4%
45 – 64	41.6%
65 – 74	22.8%
75 +	21.8%

Further data from that report also provides national statistics:

*“On December 31, 2009, more than 362,000 ESRD patients were receiving hemodialysis therapy....*

*Nine in ten prevalent hemodialysis patients had some type of Medicare coverage in 2009, with 40 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2009 reaching 10.8 and 10.2 percent for hemodialysis and peritoneal dialysis patients, respectively.”*

In Section VI.1, page 65, the applicant states, “BMA has a long history of providing dialysis services to the underserved populations of North Carolina.” Further, on page 66, the applicant states:

*“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The patient population of the FMC*

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<sup>1</sup> See, for example: [www.cms.gov](http://www.cms.gov); [www.medpac.gov](http://www.medpac.gov)

*Franklin County is expected to be similar to the facilities contributing stations to the project, and will likely be comprised of the following:*

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC Franklin County</i>	<i>27.5%</i>	<i>47.0%</i>	<i>83.5%</i>	<i>44.0%</i>	<i>73.5%</i>

*It is clear that FMC Franklin County projects to provide service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

Based on the historical utilization data provided by the applicant for its facilities in counties that are contiguous to Franklin, based on the information from CMS, and based on the projections provided by the applicant, the applicant demonstrates that it provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1(f), page 67, the applicant states:

*“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”*

In Section VI.6(a), page 68, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”* The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.1(c), page 66, the applicant states:

*“BMA believes that the economic complexion of [the counties contributing stations] is similar to Franklin County and that it is therefore appropriate to use a blended payor mix from these facilities to develop the projected payor mix for the facility.”*

<b>PAYOR SOURCE</b>	<b>PERCENT</b>
Commercial Insurance	12.0%
Medicare	79.6%
Medicaid	6.8%
VA	1.4%
Other: Self/Indigent	0.2%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant projects that 86.4% of all in-center patients would continue to have some or all of their services paid for by Medicare or Medicaid.

The applicant demonstrated that it will provide adequate access to the elderly and medically underserved populations. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.5(a), page 67, the applicant states:

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Franklin County will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”*

The applicant adequately demonstrated that it will provide a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

See Exhibit 19 for a copy of a letter to the Department Head of Nursing for Wake Tech Community College from the Director of Market Development for Fresenius Medical Care offering FMC Franklin County as a clinical training site. The applicant adequately demonstrated that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
  
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

Developing a second dialysis facility in Louisburg would introduce a competitor in Franklin County; however, the applicant failed to demonstrate how that competition would have a favorable impact on the cost effectiveness and access to dialysis services in Franklin County. Furthermore, assuming the proposal will not have a favorable impact on the cost-effectiveness and access to dialysis services in Franklin County, the applicant failed to demonstrate that dialysis is a service on which competition would not have a favorable impact. See Sections II, III, V, VI and VII of the application. In particular, see Section II, pages 26 - 30, in which the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness and access. See also Section III.1, pages 39 – 46. The information provided by the applicant in those sections is inconsistent and unreasonable, and thus fails to adequately demonstrate that the expected effects of the proposal on competition include a positive impact on cost-effectiveness and access. This determination is based on the information in the application, and on the following:

- ◆ The applicant fails to adequately demonstrate the need to develop a new 10-station dialysis facility and thus fails to demonstrate that it would be a cost-effective alternative to existing dialysis services in Franklin County.
- ◆ Since payments for dialysis services are largely set by Government payors, there is no appreciable savings to the patient as a result of competition in this instance.

- ◆ The applicant fails to demonstrate that the proposed dialysis facility would not be an unnecessary duplication of existing or approved dialysis services and facilities in Franklin County.
- ◆ The applicant further fails to demonstrate that the effects of its proposal would have a positive impact on economic access to dialysis services in Franklin County.
- ◆ The services as proposed would not enhance geographic access to dialysis services, as only 9 of the current patients are residents of the Louisburg ZIP code. A comparable number of Southwest Franklin County patients reside as close or closer to other dialysis facilities in Wake County.

Therefore, the application is not conforming to this criterion

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

The applicant currently provides dialysis services at several dialysis facilities in surrounding counties and counties contiguous to Franklin County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, those facilities have operated in compliance with all Medicare Conditions of Participation within the five months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

### NC

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is not conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

### **SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

**.2202 INFORMATION REQUIRED OF APPLICANT**

(a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*

(1) *Utilization rates;*

-C- See Section II, page 11.

(2) *Mortality rates;*

-C- See Section IV, pages 53 - 54.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- See Section IV, page 54.

(4) *The number of transplants performed or referred;*

-C- See Section IV, page 54.

(5) *The number of patients currently on the transplant waiting list;*

-C- See Section IV, page 55.

(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- See Section IV, page 55.

(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

-C- See Section IV, page 55.

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

-NC- The applicant refers to a “hospital affiliation” agreement in Exhibit 16; however, Exhibit 16 provides a copy of a transfer agreement between Wake Med Raleigh Hospital and the proposed FMC Franklin County facility. The agreement provided does not specify the relationship with the dialysis facility and describe the services that the hospital will provide to patients of the dialysis facility, as required by this rule; instead, it outlines the methods by which a patient may be transferred. The application is not conforming to this rule.

- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
  - (B) *composition of the assessment/evaluation team at the transplant center,*
  - (C) *method for periodic re-evaluation,*
  - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
  - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- C- The applicant refers to Exhibit 16 for a copy of an existing transplant agreement; however, Exhibit 16 contains a copy of a hospital transfer agreement. However, Exhibit 17 provides a copy of a signed transplantation agreement with Duke University Medical Center and FMC Franklin County which includes the information required by this rule.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- See Section II, page 14 and Exhibit 30.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- In Exhibit 12, the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- In Section II, page 14 and in Exhibits 30 and 31 provide information regarding the site on which the dialysis services are to be offered, as required by this rule.
- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- In Section XI.6(g), pages 91 - 92, the applicant provides documentation that services will be provided in conformity with applicable laws and regulations concerning staffing, fire safety, physical environment, and health and safety.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- The information regarding patient origin and all of the assumptions provided by the applicant are found in Section II, pages 14 - 18, and in Section III, pages 48 - 51 of the application.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-C- See Section II, page 18.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- The applicant states in Section II, page 19 of the application that “BMA will admit and provide dialysis services to patient who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement amount for such services.”

**.2203 PERFORMANCE STANDARDS**

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NC- The applicant provides the assumptions and methodology with which it projects the need for the new 10-station dialysis facility in Franklin County. However, the applicant did not adequately demonstrate the need for the services it proposed, because it failed to demonstrate that an adequate number of patients would dialyze at the proposed facility. Furthermore, the applicant failed to demonstrate that those patients who signed letters indicating they would transfer their care would be better served by the proposed FMC Franklin County facility. The applicant provides evidence of 22 patients who would transfer their care to the proposed facility. When the Five Year AACR for Franklin County is applied to that, the projected utilization for the first year of operation is 2.9 patients per station per week, based on 29 patients dialyzing on 10 stations. Therefore, the application is not conforming to this rule.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-NA-

(c) *An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.*

- NC- The applicant provides documentation of its assumptions in Section II, pages 20 - 24, and in Section III, pages 39 - 46. However, the applicant did not adequately demonstrate the assumptions it used were accurate and reasonable for the proposed facility, as discussed in 10A NCAC 14C .2203(a) above.

**.2204 SCOPE OF SERVICES**

*To be approved, the applicant must demonstrate that the following services will be available:*

- (1) *diagnostic and evaluation services;*  
-C- See Section V.1, page 56.
- (2) *maintenance dialysis;*  
-C- See Section V.1, page 56.
- (3) *accessible self-care training;*  
-C- See Section V.1, page 56.
- (4) *accessible follow-up program for support of patients dialyzing at home;*  
-C- See Section V.1, page 56.
- (5) *x-ray services;*  
-C- See Section V.1, page 56.
- (6) *laboratory services;*  
-C- See Section V.1, page 56, and Exhibit 18.
- (7) *blood bank services;*  
-C- See Section V.1, page 56.
- (8) *emergency care;*  
-C- See Section V.1, page 56.
- (9) *acute dialysis in an acute care setting;*  
-C- See Section V.1, page 56.
- (10) *vascular surgery for dialysis treatment patients;*  
-C- See Section V.1, page 56.
- (11) *transplantation services;*  
-C- See Section V.1, page 56, and Exhibit 17.
- (12) *vocational rehabilitation counseling and services; and*  
-C- See Section V.1, page 56.
- (13) *transportation.*  
-C- See Section V.1, page 56.

**.2205 STAFFING AND STAFF TRAINING**

(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*

-C- The applicant states in Section II that staffing at the proposed facility will be sufficient to meet the requirements in 42 CFR 405.2100. See also Section VII.1, page 69, and Section VII.10, page 72.

(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- See Section VII.5, page 70, and Exhibit 14, which includes a copy of the Fresenius Medical Care Dialysis Services Training Manual.